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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/697,079	10/27/00	FOX	[illegible]0002

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EXAMINER	
JOHANNSEN, D	

ART UNIT	PAPER NUMBER
1655	3

DATE MAILED: 01/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/697,079	Fox et al
Examiner	**Group Art Unit**
Diana Johannsen	1655

☒ Responsive to communication(s) filed on *Oct 27, 2000* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *37-43 and 45-52* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *37-43 and 45-52* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Priority

1. This application is a divisional of U.S. Application No. 09/134,672, filed August 14, 1998, now U.S. Patent No. 6,140,086, and claims the benefit of U.S. Provisional application 60/055,849, filed August 14, 1997.

Specification

2. The title of the invention is not descriptive of the subject matter of the present divisional application. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 U.S.C. § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 37-42 and 45-52 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Chenchik et al (U.S. Patent No. 5,565,340 [10/15/1996; filed 1/27/1995]).

It is noted that a recitation in a claim preamble of the intended use of a product for which a clear structural description is provided is not given patentable weight (See *MPEP 2111.02*, *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951)).

Chenchik et al teach kits comprising "antibodies that inhibit DNA polymerase activity," as well as DNA polymerases, reverse transcriptases, primers, ligases, dNTP's, and restriction endonucleases (col 11, lines 10-24). Chenchik et al teach restriction digestion of PCR products prepared using a DNA polymerase that was inactivated with anti-DNA polymerase, and thereby teach compositions comprising restriction endonucleases and polymerase inhibitors (col 20, lines 38-67; col 21, lines 1-32). With respect to claims 38-40 and 46-48, Chenchik et al teach the anti-polymerase antibodies TaqSTART (anti-Taq polymerase) and TthSTART (anti-Tth polymerase) (col 19, lines 56-57; col 21, lines 6-9). With respect to claim 49, Chenchik et al teach providing restriction endonucleases and polymerase inhibitors in kits, and thereby exemplify reagents that are "stable upon storage", as required by the instant claim (col 11, lines 10-24). With respect to claims 50-52, the compositions taught by Chenchik et al further comprise DNA polymerase, nucleic acids, and buffers (col 21, lines 28-32).

5. Claims 37-42 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Scalice et al (U.S. Patent No. 5,587,287 [12/24/1996; filed 4/7/1994]).

Scalice et al teach kits comprising thermostable DNA polymerases and inhibitors thereof, as well as other PCR reagents (col 2, lines 65-67; col 3, lines 1-20). The polymerase inhibitors

taught by Scalice et al include polymerase-specific antibodies and fragments thereof (col 7, lines 45-47; col 8, lines 1-30). With respect to claim 40, Scalice et al teach anti-Taq polymerase antibodies (col 9, lines 51-59). With respect to claim 42, Scalice et al teach kits comprising PCR reagents (col 3, line 14), and teach that PCR reagents may include primers, polymerases, and dNTPs (col 5, lines 51-55).

Claim Rejections - 35 U.S.C. § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chenchik et al (U.S. Patent No. 5,565,340 [10/15/1996; filed 1/27/1995]) in view of Ahern (The Scientist 9(15):20 [7/1995]) and the Stratagene Cloning Systems catalog (Stratagene, 1994, p. 90).

This rejection applies to claim 42 as it may be limited to kits comprising vectors and host cells. Chenchik et al teach kits comprising "antibodies that inhibit DNA polymerase activity," as well as DNA polymerases, reverse transcriptases, primers, ligases, dNTP's, and restriction endonucleases (col 11, lines 10-24). Chenchik et al disclose cloning PCR products prepared using their kit reagents (see, e.g., col 7, lines 33-41), but do not teach or suggest including in their kits vectors, competent cells, or other such cloning reagents. Ahern teaches that premade reagents provided in kit form are convenient and save researchers time and money (see p. 3/5-4/5). The Stratagene catalog teaches kits comprising reagents for cloning PCR products, which kits include vectors and competent cells. In view of the teachings of Ahern and the Stratagene catalog, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the kits of Chenchik et al so as to have included vectors and competent cells in those kits. Particularly, the teachings of Ahern would have motivated one to have modified the kits of Chenchik et al so as to have included therein any reagents necessary to practice the methods of Chenchik et al in order to have provided those reagents to practitioners in a convenient format for the advantages of efficiency and cost-effectiveness. Further, as the Stratagene catalog teaches that the reagents necessary to practice the cloning of PCR products include vectors and competent cells, an ordinary artisan would have been motivated to have

selected vectors and competent cells as particular reagents for inclusion in the kits suggested by Chenchik et al in view of Ahern for the advantage of providing in a convenient and cost-effective format the specific reagents necessary to perform the methods of cloning PCR products disclosed by Chenchik et al.

Drawings

8. It is noted that the formal drawings have been approved by the Draftsperson.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday from 7:00 a.m. to 3:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at 703/308-1152. The fax phone number for the Technology Center where this application or proceeding is assigned is 703/305-3014 or 305-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana Johannsen

January 12, 2001

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

1/12/01